

**VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING**

June 2, 2010
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463

CALL TO ORDER: The meeting was called to order at 9:10 AM.

PRESIDING: Jennifer H. Edwards, Chairman

MEMBERS PRESENT: Gill B. Abernathy
John O. Beckner
Willie Brown
Gerard Dabney
Bobby Ison
David C. Kozera
Leo H. Ross
Michael E. Stredler
Brandon K. Yi

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Dianne Reynolds-Cane, M.D., Director, DHP
Arne Owens, Chief Deputy Director, DHP
Elaine J. Yeatts, Senior Regulatory Analyst, DHP
Tiffany Mallory, Administrative Assistant (business matters)
Eusebia Joyner, Administrative Assistant (disciplinary matters)

QUORUM: With ten members present, a quorum was established.

APPROVAL OF AGENDA: An amended agenda was distributed before the meeting. With no additional changes to the amended agenda, the agenda was approved as presented.

APPROVAL OF MINUTES: The Board reviewed draft minutes for March 9, 2010; March 9, 201; March 24, 2010; April 14, 2010; April 27, 2010; May 6, 2010; May 17, 2010; May 20, 2010; and May 25, 2010. With no changes to the minutes, the minutes were approved as presented.

PUBLIC COMMENTS: There were no public comments made at this time.

DHP DIRECTOR'S REPORT: Dr. Reynolds-Cane introduced herself and Chief Deputy Arne Owens and provided further details of her background which included her years of service as a Board member and Board President for the Virginia Board of Medicine, her fellowships in

health law and health policy, and her time as medical director of The Daily Planet Health Care for the Homeless Medical Clinic, a federally qualified health center in Richmond.

ELECTION OF OFFICERS:

Mr. Ross nominated Brandon K. Yi for the office of Chairman, with a second from Mr. Dabney. No other nominations were made. The Board voted unanimously to elect Mr. Yi as Chairman for the term July 1, 2010 through June 30, 2011.

Mr. Ross nominated John Beckner for the office of Vice-Chairman, with second from Mr. Kozera. No other nominations were made. The Board voted unanimously to elect Mr. Beckner as Vice-Chairman for the term July 1, 2010 through June 30, 2011.

RECOGNITION:

Ms. Edwards, Dr. Cane, and other members of the Board recognized the five Board members whose terms were expiring and thanked them for their years of service and dedication to the Board and citizens of Virginia. Mr. Ross, Mr. Ison, and Mr. Brown are completing second terms and are not eligible for reappointment. Ms. Edwards and Mr. Stredler are finishing a first term and are eligible for reappointment.

Ms. Russell announced that she is resigning her position as Executive Director for the Board of Pharmacy as of August 1 as she is retiring from state service.

REGULATION UPDATE:

Ms. Yeatts provided the Board with an overview of regulatory processes. She stated that permanent replacement of regulations for drug donation programs and emergency regulations for CSBs are still under administrative review.

- Exempt Regulations-CE and incorrect citation

Ms. Yeatts stated that the Board needed to adopt exempt regulations to correct a conflict with statute related to the length of time to maintain CE documentation. The Board had changed the requirement to three years during its recent regulation review process for ease of auditing, but it was later discovered that the statute only requires that documents be maintained for two years. The exempt correction would change the regulation requirement back to two years to be consistent with the statute. An additional change would remove an incorrect citation in 18 VAC 110-20-690.

Motion:

The Board voted unanimously to adopt the exempt changes to regulation as presented in the agenda package. (motion by Yi, second by Kozera)

- Exempt Regulations-Electronic prescriptions

Ms. Juran reviewed draft changes to current regulations, provided as part of the amended agenda, so that the Board regulations would be in conformity with new federal rules that DEA has published,

effective June 1, 2010, allowing for electronic prescribing of Schedule II-V controlled substances. The draft changes mostly made reference to the federal regulations without repeating the language as DEA is still accepting comments on the rules and may make additional changes. Mr. Casway suggested a minor change in the definition of "electronic prescription" to make reference to the federal code cite.

Motion:

The Board voted unanimously to adopt the exempt regulation conforming Board regulations to federal regulations related to electronic prescribing of Schedule II-V controlled substances as presented in the agenda package with the addition of the federal citation in the definition of "electronic prescription". (motion by Abernathy, second by Dabney)

- Fast Track –nominal fee for duplicate licenses and written license verifications; and elimination of alarm requirement for EMS agencies that hold a CSR for the purpose of stocking only IV solutions

Ms. Russell explained that the Board has been receiving a fair number of requests for duplicate licenses particularly from pharmacy technicians who seem to lose them. Additionally, the Board receives requests from licensees who need written verification of their license status, primarily for other states in which they are licensed. License status can be verified on the department website by anyone for free, and the data is refreshed daily. Both the duplicate licenses and the written verifications take staff time away from other tasks, and cost money in terms of staff time and mailing. Other boards in the department charge a small fee for this service. Ms. Russell asked the Board to approve a nominal fee that would act as a deterrent to these requests. The draft language for fees of \$10 for duplicate licenses and \$25 for written verifications were provided in the agenda package. Ms. Russell also stated that EMS agencies may hold a CSR for the purpose of stocking their own IV solutions, and the requirement for an alarm system in this situation seemed overly burdensome. Draft language for this was also provided. Mr. Ison asked that the language make clear that the exception was only for stocking plain IV solutions with no added drug. This change was made.

Motion:

The Board voted unanimously to adopt the draft fast-track regulation establishing a fee for duplicate license and written verification requests and removing the alarm system requirements for EMS agencies stocking plain IV solutions with no added drug. (motion by Beckner, second by Brown)

- Petition for Rulemaking-addition of tramadol to Schedule IV

The Board discussed the petition to schedule tramadol as a Schedule IV controlled substance in regulation. The Board generally agreed that both tramadol and carisoprodol were known drugs of abuse, and were in agreement that they should both be scheduled, but was hesitant to begin scheduling drugs by regulation when that had always been done via legislation in the past.

Motion:

The Board voted unanimously to deny the petition for rulemaking and to circulate a legislative proposal for comment to schedule both tramadol and carisoprol as a Schedule IV controlled substance. (motion by Beckner, second by Ross)

LEGISLATION:

- 2011 Legislative Proposals
 - Compounding

Ms. Russell reviewed a draft legislative proposal changing the "or" to an "and" in § 54.1-3410.2 (F) (2) to eliminate the ability for a pharmacy to use a drug in compounding that had not been approved for use in the United States by FDA or that had merely been distributed by a registered non-resident wholesale distributor. The current structure of the language left a loophole for compounding that is inconsistent with the language in § 54.1-3421. There was some discussion as to whether this change would inadvertently affect some legitimate and safe compounding. Ms. Russell stated that if the Board approved the proposal, she would circulate the draft to IACP for comment as part of the vetting process.

Motion:

The Board voted unanimously to approve circulating this legislative draft for comment and if there were no issues to be resolved, to go forward with the proposal. (motion by Kozera, second by Dabney)

- Multiple prescriptions per order form

Ms. Russell reviewed a draft legislative proposal that would eliminate the prohibition of more than one prescription per order form in § 54.1-3408.01. She stated that this law is antiquated in light of faxed and electronic prescriptions and causing prescribers and pharmacists unnecessary workload.

Motion:

The Board voted unanimously to approve the draft legislative proposal. (motion by Abernathy, second by Ross)

- Interpretation of HB964

The Board reviewed and discussed the need for interpretation of HB964 which implements a new requirement for obtaining photo-identification in certain circumstances for persons picking up a filled Schedule II prescription. There was discussion that language in one sentence conflicted with language in another sentence. Additionally, there was some discussion as to how this law will impact pharmacies providing services to long term care facilities or other residential settings. Tim Musselman, Executive Director, VPhA, stated that they had suggested some edits to the bill to correct problems and that the patron agreed to some of the suggested changes but did not make all the changes resulting in the passed language that is inconsistent. He stated that they may ask for clarifications next session. Meanwhile, the Board determined that a guidance document clarifying current language was

necessary. Therefore, the Board interpreted that when proof of identity is required by law, a pharmacist shall make a photocopy or electronic copy of the identification or an electronic record documenting that proof of identity was provided and that whichever type of record is used, it must be maintained for at least one year.

Motion:

The Board voted unanimously to interpret the new law as recognizing that a pharmacist shall, when proof of identity is required by law, make a photocopy or electronic copy of the identification or an electronic record documenting that proof of identity was provided and that whichever type of record is used, it must be maintained for at least one year, and to put this interpretation into a guidance document. (motion by Brown, second by Kozera)

**SANCTION REFERENCE
EVALUATION:**

Neil Kauder, VisualResearch, Inc., gave the Board a brief overview of an upcoming evaluation of the sanction reference worksheets currently being used by the disciplinary committees that he plans to begin within the next few months. He stated that there have been a number of changes since the Board first implemented the system, such as the use of CCAs, cases against pharmacy technicians, and other factors that may need to be taken into consideration. He reminded the board that the Board's cases were generally similar in nature and that the sanctions had always been fairly consistent. Ms. Reiniers-Day stated that the Special Conference Committees appreciated the worksheets and would like to use them for pharmacy technicians.

**GUIDANCE DOCUMENT
REVISIONS:**

- 110-27 PIC Responsibilities

Ms. Juran reviewed draft changes to this guidance document to include inspection program changes and give more directed guidance to prospective PICs in avoiding inspection deficiencies. Mr. Ison requested that the Board require new PICs to conduct a self-inspection of the pharmacy prior to the Board granting a permit. Following discussion of the matter and Mr. Casway's statement that unless it was a requirement of law or regulation, the Board could not require it, the Board came to an agreement that this was not feasible. After further discussion, there was a consensus that a copy of the guidance document and website link to the inspection form could be attached to the application, and that there could be an attestation on the pharmacy permit application for designating a new PIC to state that the PIC had reviewed the materials related to potential monetary penalties associated with inspection deficiencies. Additionally, the draft guidance document was amended to include the word "strongly" related to the suggestion that the PIC conduct a self-inspection of the pharmacy.

Motion:

The Board voted unanimously to adopt the guidance document as amended and include an attestation on the application that the new PIC has read and understood guidance document 110-27 and the associated information regarding the inspection process. (motion by Ison, second by Dabney.)

- 110-34 Wholesale Distributors

Ms. Juran explained that this is an existing guidance document regarding licensure requirements that is provided to nonresident manufacturers and wholesale distributors that do not physically ship prescription drug into Virginia, but rather use a third party logistics company to physically ship the drug. Due to similar licensure questions received recently by staff for facilities located in Virginia using a third party logistics company to ship drugs, Ms. Juran discussed amended language that would similarly address those licensure issues.

Motion:

The Board voted unanimously to adopt the guidance document amendments as presented with the agenda. (motion by Kozera, second by Ross)

- 110-35 Prescription Requirements

The Board reviewed draft changes to this guidance document to conform with changes related to the new DEA electronic prescribing regulations.

Motion:

The Board voted unanimously to approve the changes to the guidance document. (motion by Ross, second by Brown)

- 110-9 Inspection Monetary Penalty Guide

Ms. Juran reviewed the draft changes to this guidance document based on lessons learned while piloting the new procedures, as well as changes recommended by the ad hoc committee for inspecting for compliance with USP 797 and USP 795. Ms. Abernathy suggested amending the draft language as presented for major deficiency 25 to clarify that the deficiency for improperly storing drugs intended to only address the storage of drugs intended for use.

Motion:

The Board voted unanimously to approve this guidance document with the amendments. (motion by Beckner, second by Ison)

MISCELLANEOUS:

- Update on the inspection program

Ms. Juran reviewed statistics resulting from the 105 pilot inspections of retail pharmacies performed through May 20, 2010, explaining that 30% of the inspections would have resulted in no deficiencies, 33% would have resulted in a cited deficiency and 36% would have resulted in a monetary penalty. She and Sammy Johnson, Assistant Director of Enforcement, confirmed that the

overall piloting process was going well and that inspectors planned to go live with retail/community pharmacy inspections in the first part of July 2010. Inspectors will continue to telephone retail/community pharmacies until September 1, 2010, alerting them that an inspection will be performed sometime within the following two weeks. After September 1, 2010, inspections will again be performed unannounced. Additionally, Ms. Juran reviewed the draft inspection report for USP 797 and USP 795 resulting from the recently held committee meeting. There was discussion regarding the documentation for evaluation of airborne microorganisms in the controlled air environment and how often this evaluation must be performed. Mr. Ison recommended at least every six months which could be performed during the certification process of the ISO environments and the Board concurred. Additionally, Ms. Abernathy recommended amending the language regarding the daily accuracy assessment of automated compounding devices so that it did not solely address devices used only for parenteral nutrition compounding, but addressed automated compounding devices in general. The Board agreed with her suggestion. Ms. Juran and Mr. Johnson then explained that the inspectors planned to begin piloting the new inspection process in the hospital or other institutional pharmacies in July and would provide notifications similar to those provided to the retail/community pharmacies. No monetary penalties will be issued to the hospital or institutional pharmacies during this piloting phase.

- Changes to HIPDB/NPDB reporting

Ms. Russell advised the Board that the national databases HIPDB and NPDB were eventually going to be merged into one databank, but that a new requirement became effective as of January 2010 for agencies to report actions currently and previously taken against health care entities, specifically pharmacies, as well as certain health care professionals. The agency has been reporting actions against pharmacists for years, but has not been reporting pharmacies as it was not a requirement. The data department is now obtaining back data for pharmacies reported and will be including these actions in future reporting. This will also mean that with the new inspection deficiencies being docketed against the pharmacy permit, there will be an increase in pharmacies reported to the databases. There was some discussion about the appropriateness of docketing against the pharmacy permit versus the PIC, and the Board did not make any changes at this time to its original direction to docket against the pharmacy permit.

- Pharmacy Residents

Mr. Ison had asked that the Board discuss the problem with pharmacy residencies beginning July 1 and some residents not having obtained their pharmacist license by that time. He wondered if there was some way to expedite the process. Ms. Russell stated

that for most persons graduating in May, there was no reason why they could not be licensed by July 1, provided they passed the NAPLEX and law exam on the first try. She stated that she really had no way to expedite the process anymore than it was.

- Pharmacy Coupons

Ms. Edwards reviewed a letter received by the Board from a pharmacy student at VCU expressing concern for the “widespread use” of pharmacy coupons explaining that he believed it created a patient safety issue for persons to have multiple prescriptions at multiple pharmacies and impedes a pharmacist’s ability to perform a satisfactory prospective and/or retrospective DUR process. There was much discussion regarding the pros and cons of pharmacy coupons. Ms. Russell explained that prohibiting the use of coupons may be considered a restraint of trade, but thought New York and New Jersey may currently have restrictions on their use. The Board requested staff to research this topic through NABP to determine how this issue is being addressed nationally.

BOARD OF HEALTH
PROFESSIONS (“BHP”)
REPORT:

Ms. Edwards gave the Board an update on BHP activities to include new advisory boards for the Board of Medicine to regulate polysomnographers and surgical assistants and/or technicians. BHP will also be reviewing kinesiotherapists, medication aides in nursing homes, and genetic counselors to determine if there is a need for licensure or registration through DHP.

EXECUTIVE DIRECTOR’S
REPORT:

Ms. Russell gave a brief report of resolutions adopted at the recent NABP meeting. Her report included a Recognition Resolution that acknowledged the deaths of Carl F. Emswiller, Jr. and S. Wallace Cunduff, former Board members, stating that they had made significant contributions to NABP, the protection of the public health, and the profession of pharmacy.

Additionally, Ms. Russell stated that she would be attending a DEA Meeting in two weeks.

Jennifer Edwards departed at 2:00 p.m.

SUMMARY SUSPENSION:

Closed meeting:

Mr. Kozera moved, and the Board voted unanimously, to convene a closed meeting pursuant to § 2.2-3711.A.27 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of a possible summary suspension. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, Caroline Juran, Eusebia Joyner, Howard Casway, Wayne Halbleib and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.

DORIAN DOWNHAM
Pharmacy Technician
Registration Number:
0230-003973

Wayne Halbleib, Senior Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a summary suspension. Mykl D. Egan, DHP Adjudication Specialist, was also present.

Reconvene:

Mr. Kozera moved, and the Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

Decision:

Mr. Kozera moved, and the Board voted unanimously in favor of the motion that, with the evidence presented, the pharmacy technician practice by Dorian Downham poses a substantial danger to the public; and therefore, the registration of Dorian Downham to practice as a pharmacy technician be summarily suspended; and that a Consent Order be offered to Ms. Downham for the indefinite suspension of her registration for not less than two (2) years in lieu of a formal administrative hearing.

FORMAL ADMINISTRATIVE HEARING

JERMAINE L. MOON
Pharmacy Technician
Registration Number:
0230-003098

Brandon Yi presided as the Chairman for a formal administrative hearing held in the matter of Jermaine L. Moon. The hearing was held to discuss his petition for reinstatement of his pharmacy technician registration that was mandatorily suspended on December 1, 2009, and allegations that he may have violated certain laws or regulations governing the practice of pharmacy technicians in Virginia.

Wayne T. Halbleib, Senior Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist. Mr. Moon appeared and was not represented by counsel.

Ann S. Hardy, DHP Senior Investigator, testified on behalf of the Commonwealth.

Jermaine L. Moon testified on his own behalf.

Closed Meeting:

Mr. Kozera moved and the Board voted unanimously, to enter into a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Jermaine L. Moon. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day and Howard Casway attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation

Reconvene: Mr. Kozera moved, and the Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

Decision: Mr. Dabney moved, and the Board voted unanimously, to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib, amended by the Board and read by Mr. Casway.

Mr. Dabney moved, and the Board voted eight in favor of the motion, that Mr. Moon's petition for the reinstatement of his pharmacy technician registration be denied.

ADJOURN: With all business concluded, the meeting adjourned at 4:15 p.m.

Elizabeth Scott Russell
Executive Director

Jennifer Edwards, Board Chairman

Brandon K. Yi, Formal Administrative
Hearing Chairman

Date

Date